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STATE OF NEW MEXICO COUNTY OF DOÑA ANA THIRD JUDICIAL DISTRICT COURT

THE STATE OF NEW MEXICO, ex rel. HECTOR BALDERAS, ATTORNEY GENERAL,

Plaintiff,

v.

STERIGENICS U.S., LLC, SOTERA HEALTH HOLDINGS, LLC, SOTERA HEALTH LLC, and SOTERA HEALTH COMPANY,

Defendants.

No.: D-307-CV-2020-02629

Beyer, Marci

VERIFIED COMPLAINT WITH JURY
DEMAND AND EX PARTE REQUEST FOR
TEMPORARY RESTRAINING ORDER
AND PRELIMINARY INJUNCTION

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I. INTRODUCTION

- 1. The State of New Mexico, by its Attorney General Hector Balderas ("Plaintiff" or "New Mexico" or the "State"), brings this action against Defendants Sterigenics U.S., LLC, Sotera Health Holdings, LLC ("Sotera Holdings"), Sotera Health, LLC, and Sotera Health Company ("Sotera") (collectively, "Defendants" or "Sterigenics"), for all damages to New Mexico recoverable at law or in equity, and for declaratory and injunctive relief, to remedy Defendants' violations of law.
- 2. Sterigenics holds itself out as "the global leader in comprehensive sterilization solutions serving customers' industrial sterilization needs across the medical device, pharmaceutical, advanced applications, commercial, and food industries."
- 3. Since 1989, Defendants have owned and operated a large facility in Santa Teresa, Doña Ana County, New Mexico, at which industrial sterilization and fumigation processes have been and continue to be employed (the "Santa Teresa Plant" or the "Plant").
- 4. The Santa Teresa Plant is located in a business park on Airport Road in Santa Teresa, proximate to a number of residential communities and schools.
- 5. Doña Ana County, and Santa Teresa specifically, are minority-majority communities.
- 6. Since 1989, Defendants have used and continue to use substantial quantities of a highly toxic, carcinogenic air pollutant, ethylene oxide ("EtO"), in their industrial sterilization processes at the Santa Teresa Plant.
- 7. EtO is genotoxic (i.e., it damages DNA) and is known to cause cancer, including lymphoma, leukemia, stomach cancer, and breast cancer.

- 8. The National Toxicology Program, a federal program, has recognized EtO as a known human carcinogen since 2000, and as a likely human carcinogen since 1985.
- 9. Even at very low levels, inhalation of EtO-contaminated air significantly increases the risk of developing cancer and other adverse health effects.
- 10. In December 2016, the U.S. Environmental Protection Agency's ("EPA") Integrated Risk Information System ("IRIS") program released an evaluation of EtO carcinogenicity (the "2016 IRIS Evaluation"), which characterized EtO as "carcinogenic to humans" and noted that EtO is a mutagenic carcinogen that causes cancer by damaging DNA in cells, which is then duplicated when the cells divide.
- 11. As outlined in the 2016 IRIS Evaluation, EtO exposure increases the cancer risk because DNA damage can take place with each and every exposure that is passed on to more cells, thereby increasing the number of mutated cells.
- 12. Based on this concern, the 2016 IRIS Evaluation increased the EPA lifetime inhalation risk estimate by a factor of about 30.
- 13. In conjunction with the 2016 IRIS Evaluation, EPA has established inhalation unit risk ("IUR") estimates for exposure to EtO in ambient air in order to evaluate the potential cancer risks posed by inhalation exposure to EtO.
- 14. The EPA's IUR estimates for cancer mortality and incidence were based on the human data from a National Institute for Occupational Safety and Health ("NIOSH") study. This study was selected for the derivation of risk estimates because it was deemed a "high-quality" study.
 - 15. The IUR established for EtO is .03 ug/m³ (micrograms per cubic meter).

- 16. Once released into air, EtO can travel significant distances with air currents, and can remain in ambient air for over 200 days.
- 17. EtO emitted by Defendants from the Santa Teresa Plant has significantly deteriorated air quality in Santa Teresa and surrounding communities for decades, and has materially contributed to increased health risks suffered by residents of such communities.
- 18. Since 1989, Defendants have reported emitting several tons of EtO per year from the Santa Teresa Plant through controlled sources, including sterilizer vacuum pumps, acid-water scrubbers, and catalytic oxidizers.
- 19. However, Defendants have also caused substantial unreported, uncontrolled releases of EtO to the atmosphere from the Santa Teresa Plant as a result of their intentional or negligent subversion of environmental controls:
 - a. As revealed in the State's presuit investigation, due to Defendants' lax oversight in connection with sterilization operations—such as the practice of routinely leaving sterilization chamber doors ajar between sterilization cycles—EtO levels in the ambient indoor air at Defendants' Santa Teresa Plant were often elevated, as indicated by an air-quality monitoring system. To dissipate the elevated concentrations of EtO inside the Plant, Defendants caused shipping bays and large facility doors to be left open for hours, or entire days, releasing excess EtO into the atmosphere in an uncontrolled and unfiltered manner.
 - b. Further, during regular cleaning and maintenance operations, on an at least monthly basis, Defendants caused EtO and ethylene glycol residues built up within the sterilization chambers to be removed from sterilization equipment using a hose and

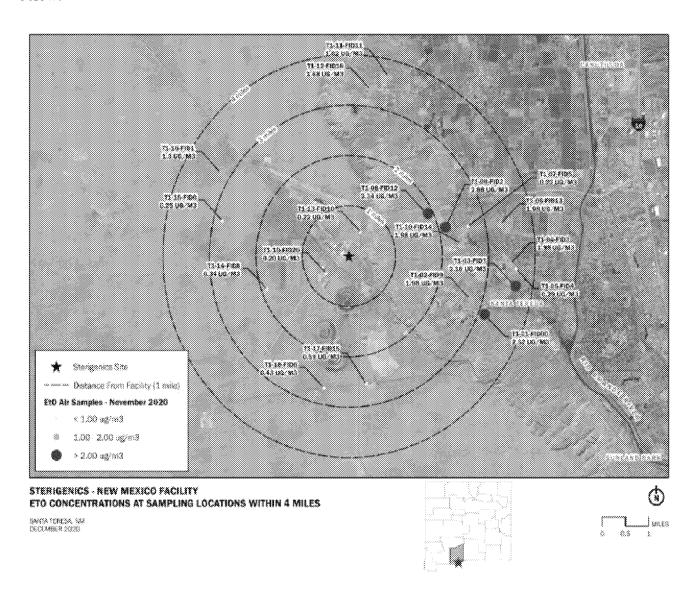
released through an ordinary drain. This practice resulted in the uncontrolled release of EtO and ethylene glycol into the environment.

- c. The Santa Teresa Plant also assisted other Sterigenics facilities in performing sterilization operations, including aeration of sterilized products. For example, Sterigenics caused shipments of sterilized devices and equipment to be delivered to the Santa Teresa Plant from the company's San Diego facility on a near-weekly basis so that such devices and equipment could be aerated for 24 hours in the Santa Teresa Plant. As these shipments had been sterilized using EtO, but not aerated, they were off-gassing EtO during the shipping, receiving, and loading phases, including at the Santa Teresa Plant, further contributing to the uncontrolled release of EtO in the State.
- 20. Uncontrolled emissions also escaped the Santa Teresa Plant from the sterilization back vents at the facility, which were not routed through an emission control system until as late as 2014, and through other means, which may include emissions released during mechanical failures or breakdowns impacting the Plant's emission control systems.
- 21. In August 2018, the EPA published results from its 2014 National Air Toxics Assessment ("NATA") study. The study compiled evidence showing that, due to Defendants' reported emissions of EtO, residents of Santa Teresa and surrounding locations are at a statistically significantly increased risk of developing cancer. The NATA study assessed the increased cancer risk due to EtO exposure in Doña Ana County based on 2014 emissions data reported by Sterigenics.
- 22. In 2014, Sterigenics substantially decreased its reported EtO emissions as compared to prior years; from 1989 to 2013, Defendants reported emitting thousands more pounds of EtO as compared to 2014.

- 23. Accordingly, the NATA study greatly underestimates the historic impact of Defendants' EtO emissions, and the increased cancer risk in Doña Ana County.
- 24. The NATA data shows that, as of 2014, Doña Ana County residents in the census tract likely suffering the most exposure to EtO have a cancer risk of **214.5543 per 1 million**, which is far in excess of the national average (approximately 30 per 1 million), and that this increased risk is due to EtO exposure. For years prior to 2014, the risk is considerably higher.
- 25. The NATA data similarly shows that Doña Ana County residents in nearby census tracts suffer increased cancer risk due to EtO exposure.
- 26. Because the Santa Teresa Plant is the only significant source of EtO in the Santa Teresa region, and was the sole source of EtO taken into account with respect to the cancer risk assessment of Doña Ana County residents in the NATA study, this increased cancer risk is wholly or substantially attributable to Defendants' operations.
- 27. All residents of Doña Ana County (approximately 218,195 residents) are affected by Defendants' EtO emissions, according to the NATA study.
- 28. Defendants have reported emitting hundreds of thousands of pounds of EtO from the Santa Teresa Plant from 1989 to 2016, including at least 10,000 pounds of EtO per year from 2005 to 2013.
- 29. As revealed in the State's presuit investigation, however, Defendants have caused excessive uncontrolled EtO and ethylene glycol emissions into the environment in the State as a result of deficient environmental controls and intentional subversion of environmental controls.
- 30. Beyond the cancer risk identified by the NATA data associated with the Santa Teresa Plant, the State's presuit investigation included sampling of ambient outdoor air within a

four-mile radius of the Santa Teresa Plant for EtO. This investigation confirmed the substantial risk to New Mexico residents based on Defendants' EtO emissions.

31. Every one of the air samples collected in the presuit investigation within a four-mile radius of the Santa Teresa Plant detected ambient airborne concentrations in excess of the EPA IUR of .03 ug/m³, including one sample that was **96 times the EPA's cancer risk level** (measured at 2.88 ug/m³). A map showing the exceedances of the EPA's IUR threshold appears below:



- 32. In the map above, every sample indicator (yellow, orange, or red) represents an exceedance of the EPA IUR level. None of the sampling events showed EtO detections below that level.
- 33. Defendants' emissions of EtO from 1989 until the present have caused significant harm to New Mexico and its residents.
- 34. For example, Defendants' EtO emissions have severely impacted air quality in Santa Teresa and Doña Ana County. Past and future increased healthcare costs associated with Defendants' industrial activities constitute a financial loss to the State, including by increasing the cost of treating affected residents and by expenditures of State financial resources through State healthcare programs and plans.
- 35. Defendants' conduct has also caused property values in the affected census tracts to decline.
- 36. The increased risk of adverse health effects and diminution of property values in the affected communities similarly constitute injuries to New Mexico residents.
- 37. Through this action, the State, acting as *parens patriae* and on its own behalf, seeks all damages available under law, including compensatory and punitive damages, and all other monetary relief, declaratory relief, and injunctive relief necessary and appropriate to remedy Defendants' unlawful conduct, including a temporary restraining order and preliminary injunction requiring Defendants to cease any and all uncontrolled emissions or releases of EtO from the Santa Teresa Plant.

II. JURISDICTION AND VENUE

38. The property and conduct that are the subject of this suit all rest within the State of New Mexico. No federal subject-matter jurisdiction exists or is invoked herein.

- 39. Venue is proper in Doña Ana County pursuant to NMSA 1978 Section 38-3-1 because a plaintiff resides here and the defendants are foreign corporations, and the causes of action asserted herein arose in this County.
- 40. This Court has subject matter jurisdiction over this case pursuant to N.M. Const. Art. VI, Sec. 13.
- 41. This Court has personal jurisdiction over Defendants pursuant to both NMSA 1978 Section 38-1-16(A) and New Mexico's "sufficient minimum contacts" test. *Sproul v. Rob & Charlie's, Inc.*, 2013-NMCA-072, ¶ 13, 304 P.3d 18. Defendants currently or formerly owned and/or operated at least one facility in Santa Teresa, Doña Ana County, New Mexico.

III. PARTIES

A. PLAINTIFF

- 42. The State of New Mexico is a body politic created by the Constitution and laws of the State; as such it is not a citizen of any state.
- 43. The State of New Mexico, by the Honorable Hector H. Balderas, Attorney General of the State of New Mexico, brings this suit because, in his judgment, it is in the state's interest to do so and pursuant to its inherent *parens patriae* authority to remedy an injury to its "quasi-sovereign interest" in the physical and economic health and well-being of a substantial segment of its population.
- 44. The Attorney General is authorized to act on behalf of the State in all actions when the interests of the State require action in his judgment, is empowered to prosecute all actions and proceedings brought by any State officer or head of a State department, board, or commission, or any employee of the State in his official capacity, and is empowered to appear before local, state,

and federal courts to represent the State when, in his judgment, the public interest of the State requires such action. NMSA 1978 Section 8-5-2(B)-(C), (J).

- 45. New Mexico enjoys *parens patriae* standing in this suit because its residents have been adversely affected by the presence of EtO in the State's environment as alleged herein, including suffering property diminution, increased risks of adverse health effects, and/or suffer loss through monetary assessments or expenditures that contribute to the assessment, monitoring, and analysis of EtO and contaminants resulting from EtO emissions and to coverage for increased healthcare costs associated with EtO exposure.
- 46. New Mexico has spent and will continue to spend money in connection with the misconduct alleged herein, including costs associated with monitoring and assessing EtO contamination, and healthcare costs associated with New Mexico residents' exposure to Defendants' EtO emissions.
- 47. Further, the Attorney General has the authority to enforce the New Mexico Unfair Practices Act, NMSA 1978 §§ 57-12-1, *et seq.* ("UPA"), and the New Mexico public nuisance statute, NMSA 1978 §§ 30-8-1, *et seq.* ("Public Nuisance Statute"), to ensure the protection of New Mexico residents, natural resources, and commerce.

B. DEFENDANTS

- 48. Defendant Sterigenics U.S., LLC is a limited liability company organized under the laws of the State of Delaware with its principal place of business in the State of Illinois. Sterigenics U.S., LLC operates the Santa Teresa Plant.
- 49. Defendant Sotera Holdings is a limited liability company organized under the laws of the State of Delaware with its principal place of business in the State of Ohio. The Santa Teresa Plant is currently owned by Sotera Holdings, and has been owned by that defendant since 2018.

- 50. Defendant Sotera Health, LLC is a limited liability company organized under the laws of the State of Delaware with its principal place of business in the State of Ohio. Sotera Health, LLC was formerly known as Sterigenics International.
- 51. Defendant Sotera Health Company is a publicly traded company organized under the laws of the State of Delaware with its principal place of business in the State of Ohio. Sotera Health Company's shares are listed on the NASDAQ exchange under ticker symbol SHC. Sotera Health Company is the parent company of each of the other Defendants.
- 52. The Santa Teresa Plant was originally owned by Griffith Micro Science, Inc. ("Griffith"). Griffith, along with Sterigenics International, was acquired by Ion Beam Applications S.A. ("IBA") in 1999. IBA was subsequently renamed Sterigenics International, Inc. in 2004.

IV. FACTUAL ALLEGATIONS

A. ETHYLENE OXIDE IS A DANGEROUS POLLUTANT THAT THREATENS HUMAN AND ENVIRONMENTAL HEALTH AND SAFETY

1. Physical and Chemical Properties of EtO.

- 53. Ethylene oxide, or EtO, is a flammable, colorless, highly penetrating gas used to sterilize or fumigate heat- and moisture-sensitive products, equipment, and devices that cannot be sterilized by steam.
 - 54. EtO is water soluble.
- 55. In air or soil, EtO breaks down over time. EPA estimates that atmospheric degradation of EtO, at 25 degrees Celsius/77 degrees Fahrenheit, occurs over 69-149 days. The World Health Organization ("WHO") estimates that the "half-life of ethylene oxide in the atmosphere" is 211 days, and notes that "[n]either rain nor absorption into aqueous aerosols is capable of removing ethylene oxide from the atmosphere."

- 56. At atmospheric pressure and room temperature, EtO exists as a gas due to its high vapor pressure and low boiling point.
- 57. Due to its high vapor pressure, EtO has a strong tendency to escape (volatilize) into air from soil or water (or other environmental media or compartment).
- 58. EtO is heavier and denser than air. Accordingly, the WHO reports that EtO "may travel along the ground," i.e., at a height at which emitted EtO may be inhaled, once released.
 - 59. EtO is rapidly absorbed by the human body after inhalation or dermal exposure.
- 60. The half-life of EtO in the body following inhalation is 45-60 minutes. Full elimination from the body occurs within 1-7 days after exposure.
- 61. When EtO is present in the air continuously, EtO levels are continuously present in the bodies of those exposed.
- 62. Insufficient use of scrubbing technologies and other standard measures to limit or reduce emissions of potentially hazardous chemicals is responsible for most air emissions of EtO from industrial facilities, such as Defendants' Santa Teresa Plant.
 - 63. There is no safe amount of EtO in air or other environmental media.
- 64. Unfiltered or uncontrolled emissions of EtO represent a significant cause for concern because much larger volumes of EtO may be released in the absence of scrubbers and other standard environmental control technologies, which serve to limit the volume of EtO released to the atmosphere.

2. Health Effects of Exposure to EtO.

- 65. Humans are exposed to EtO primarily by inhaling contaminated air, particularly near industrial facilities emitting EtO.
 - 66. EtO causes a wide variety of adverse health effects in exposed persons.

- 67. Studies of workers exposed to EtO as well as animal studies demonstrate that EtO exposure results in eye, skin, and mucous membrane irritation, impaired neurological functioning, increased rate of miscarriages in females and other reproductive deficiencies, low birth weight, delayed bone formation, and cancer, including an increased risk of leukemia, stomach cancer, pancreatic cancer, breast cancer, non-Hodgkin's lymphoma, Hodgkin's disease, brain tumors, lung tumors, and tumors of the tear duct.
- 68. Respiratory effects of EtO exposure include mucous membrane irritation, bronchitis, pulmonary edema, and emphysema.
- 69. Neurological effects of EtO exposure include headache, nausea, vomiting, peripheral neuropathy, impaired hand-eye coordination, memory loss, loss of balance, lethargy, numbness and weakness of the extremities, and brain lesions.
- 70. Fetuses in the womb are also exposed to EtO through their mothers. Animal studies of EtO exposure demonstrate that embryo and fetal toxicity, including increased incidence of resorption, reduced fetal body weight and length, and reduced skeletal ossification of the skull and sternebrae.
- 71. Other adverse reproductive effects of EtO exposure include decreased implantation rates, decreased testicular weights and testicular degeneration, and interference with sperm concentration, motility and drive range.
- 72. EtO is also genotoxic. The DNA-damaging properties of EtO have been studied for decades. It is known to be mutagenic in many organisms, from bacteriophage to mammals, and induces chromosome damage.
- 73. Studies of peripheral blood lymphocytes resulted in detection of chromosomal aberrations including breaks, gaps, and exchanges and supernumerary chromosomes, and other

studies report increased incidence of SCE (sister chromatid exchange) in the peripheral lymphocytes of exposed workers and animals, which appears to be a permanent interference with the exposed organism's genetic information.

- 74. EtO is highly carcinogenic. The National Toxicology Program has, since 2000, recognized EtO as a known human carcinogen, and as a likely human carcinogen since 1985.
- 75. The WHO categorizes EtO as "carcinogenic to humans" and has acknowledged there is "strong evidence that the carcinogenicity of ethylene oxide ... operates by a genotoxic mechanism."
- 76. According to EPA, EtO "is carcinogenic in mice and rats, inducing tumors of the lymphohematopoietic system, brain, lung, connective tissue, uterus, and mammary gland." In humans, "there is strong evidence of an increased risk of cancer of the lymphohematopoietic system and of breast cancer in females."
- 77. One large epidemiologic study of sterilizer workers, conducted by the NIOSH and published in 1991 in the *New England Journal of Medicine*, reported positive exposure-response trends for lymphohematopoietic cancer mortality, primarily in men and particularly for lymphoid cancer (non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia) and for breast cancer mortality in women.
- 78. EPA characterizes EtO as "carcinogenic to humans' by the inhalation route of exposure based on the total weight of the evidence."
- 79. This characterization is based on strong epidemiological evidence, extensive evidence of carcinogenicity in laboratory animals, clear evidence of genotoxicity and sufficient evidence to support a mutagenic mode of action for EtO carcinogenicity, and strong evidence that

the key precursor events are anticipated to occur in humans and progress to tumors, including evidence of chromosome damage in humans exposed to EtO.

- 80. EPA classifies its confidence level in characterizing EtO as a carcinogen to humans by the inhalation route as "high."
- 81. EPA's conclusion that EtO is carcinogenic to humans (as distinguished from being potentially carcinogenic to humans) was announced in late 2016, as detailed further below, in connection with the 2016 IRIS Evaluation.
- 82. The 2016 IRIS Evaluation was an EPA program to assess the carcinogenicity of EtO. The Evaluation found that EtO is carcinogenic to humans and, in particular, that EtO is a mutagenic carcinogen that causes cancer by damaging DNA in cells, which is then duplicated when the cells divide.
- 83. As explained in the 2016 IRIS Evaluation, EtO exposure increases the cancer risk because DNA damage can take place with each and every exposure that is passed on to more cells, thereby increasing the number of mutated cells.
- 84. Based on these findings, EPA increased its inhalation risk estimate for EtO by a factor of about 30.
- 85. The EPA IUR (inhalation unit risk), developed in conjunction with the 2016 IRIS Evaluation, is .03 ug/m³ (micrograms per cubic meter).
- 86. Exposure to EtO concentrations above the IUR threshold represents an increase in cancer risk.

B. DEFENDANTS KNEW ETO WAS A DANGEROUS POLLUTANT

87. The Santa Teresa Plant opened and began using and emitting EtO in or around 1989.

- 88. Over a decade earlier, in August 1977, the NIOSH issued a "Special Occupational Hazard Review with Control Recommendations for Use of Ethylene Oxide as a Sterilant in Medical Facilities."
- 89. The NIOSH review advised EtO users that "[r]ecent results of tests for mutagenesis have increased the concern for potential health hazards associated with exposure to EtO."
- 90. The review noted that "acute toxic effects of EtO in man and animals include acute respiratory and eye irritation, skin sensitization, vomiting, and diarrhea. Known chronic effects consist of respiratory irritation and secondary respiratory infection, anemia, and altered behavior."
- 91. Although data was limited at the time, the review further advised of the potential for carcinogenicity of EtO due to its ability to alter the structure of genetic material.
- 92. "[T]he alkylating and mutagenic properties of EtO are sufficient bases for concern about its potential carcinogenicity," according to NIOSH in 1977. Accordingly, NIOSH recommended that EtO be considered as "mutagenic and potentially carcinogenic to humans."
- 93. NIOSH recommended reducing or eliminating use of EtO for medical sterilization purposes, where alternative processes exist, to protect human health.
- 94. NIOSH's 1977 review identified a variety of deficiencies in sterilization facilities using EtO, including "improper or inadequate ventilation" and "poor design of the sterilization facility," among others. The review further notes that "[w]hen proper control measures are instituted, the escape of EtO into the environment will be greatly reduced."
- 95. NIOSH published a document entitled "Ethylene Oxide (EtO): Evidence of Carcinogenicity" in 1981, concluding that EtO should be considered a potential occupational carcinogen.

- 96. EtO was designated as a likely human carcinogen by the National Toxicology Program in 1985, and as a known human carcinogen by the State of California in 1987.
- 97. Defendants operated at least two facilities using EtO in their sterilization processes in the State of California in 1987. Accordingly, Defendants were aware that the chemical was being regulated as a carcinogen in that state before opening the Santa Teresa Plant in 1989.
- 98. The large, well-validated NIOSH epidemiologic study of sterilizer workers, which appeared in the *New England Journal of Medicine* and was subsequently relied upon by EPA, was published in 1991. That study examined health effects of EtO exposure in 18,254 sterilization workers in the United States, including Sterigenics workers.
- 99. Studies published in 2003 and 2004 by the same authors confirmed certain findings detected in the 1991 study, including that EtO exposure was associated with breast cancer in women and with hematopoietic cancer in men, with greater incidences of each positively associated with increased EtO exposure.
- 100. In an effort to rebut these studies and their regulatory impact, Sterigenics' Senior Vice President of Global Environmental Health & Safety, Kathleen Hoffman, issued a letter dated November 12, 2014, directed to the Science Advisory Board (SAB) of EPA.
- 101. In the letter, Ms. Hoffman claims that increased regulation of EtO sterilization processes would disrupt healthcare and medical device supply chains, and impose significant costs on companies in those supply chains. The letter expressly challenges the NIOSH studies referenced above because they incorporate data from workers subjected to workplace controls that have evolved over time.
- 102. In other words, the basis for Sterigenics' opposition to EPA's reliance on the NIOSH studies is that companies like Sterigenics have gradually reduced worker exposure to EtO,

as required by a series of revised exposure limits issued by scientific and regulatory bodies over the past 6 decades—not that the study is inaccurate or invalid, and not that its consequences for environmental and public health regulatory purposes have been misunderstood.

- 103. EPA rejected Sterigenics' entreaties and cemented its reliance on the NIOSH studies in 2016, confirming that EtO is a human carcinogen by the inhalation exposure route, as described above.
- 104. As regulators increased their scrutiny of EtO and EtO emitters (and Sterigenics in particular) after 2016, Sterigenics continued to push back, claiming that increased regulations will result in supply chain disruptions in the healthcare and medical device industries. In light of these arguments, EPA asked the U.S. Food & Drug Administration ("FDA") to express its views on the matter.
- 105. In a letter dated February 5, 2020, Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health, confirmed that, in FDA's view, "EPA should establish EtO emissions limits based on the levels necessary to protect human health and the environment from EtO toxicity."
- 106. Dr. Shuren's letter notes that "FDA looks to EPA to set allowable limits for EtO emissions since FDA does not have the authority to do so. Contract sterilizers and medical device manufacturers must comply with the EtO standards and guidelines that EPA sets and FDA is committed to working with these entities to reduce the amount of EtO used and to explore the use of alternatives as appropriate. If a facility is unable to meet EPA emissions limits and its inability to do so could lead to product availability concerns, FDA will work with the facility and other entities in the supply chain to mitigate these concerns."

107. Accordingly, Dr. Shuren's letter confirms that Sterigenics' supply chain disruption

narrative is faulty, because FDA has committed to working with sterilizers and medical device

companies to ensure emissions controls do not pose a threat to product availability.

C. DEFENDANTS' RELEASES OF ETO FROM THE SANTA TERESA PLANT SINCE

1989

108. The Santa Teresa Plant is a 105,000 square foot facility located in a business park

in Santa Teresa, six miles from New Mexico's border with Mexico.

109. The Plant is located approximately 2 miles from schools, churches, and

neighborhoods in Santa Teresa, home to thousands of residents, and situated among dozens of

other businesses and workplaces employing over a thousand New Mexico residents.

110. From 1989 to the present, hundreds of thousands of pounds, or more, of EtO used

at the Santa Teresa Plant to sterilize and/or fumigate products and devices were released into the

air following the sterilization and/or fumigation process.

Defendants issued voluntary annual reports of EtO emissions from the Santa Teresa

Plant covering the years 1994 to 2016. From 2017 onward, Defendants have declined to release

such disclosures.

The reports that were made dramatically understate the actual EtO emissions from 112.

this facility.

113. Defendants' self-reported EtO air emissions from the Santa Teresa Plant, for the

years 1994 to 2016, are as follows:

a. 1994: 250 lbs.

b. 1995: 300 lbs.

c. 1996: 640 lbs.

d. 1997: 1,100 lbs.

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- e. 1998: 5,970 lbs.
- f. 1999: 5,318 lbs.
- g. 2000: 4,675 lbs.
- h. 2001: 5,044 lbs.
- i. 2002: 5,026 lbs.
- j. 2003: 6,752 lbs.
- k. 2004: 7,123 lbs.
- 1. 2005: 11,756 lbs.
- m. 2006: 14,759 lbs.
- n. 2007: 14,022 lbs.
- o. 2008: 15,439 lbs.
- p. 2009: 11,485 lbs.
- q. 2010: 12,421 lbs.
- r. 2011: 13,068 lbs.
- s. 2012: 12,362 lbs.
- t. 2013: 10,082 lbs.
- u. 2014: 5,761 lbs.
- v. 2015: 1,003 lbs.
- w. 2016: 967 lbs.
- 114. Notably, for the self-reported quantities set forth above, Defendants assumed very low amounts of uncontrolled or fugitive emissions of EtO (approximately 500 lbs. per year).
- 115. In fact, however, Defendants' routine operational and maintenance practices resulted in significant unreported, uncontrolled EtO emissions.

- and handled hundreds of thousands, and frequently over one million, pounds of EtO each year. A substantial portion of this volume was released into air through uncontrolled or fugitive releases that Defendants failed to report.
- 117. Indeed, prior to 2014, when Defendants rerouted nine of the sterilization back vents through the Plant oxidizer to reduce emissions from this part of the facility, all nine back vents resulted in uncontrolled emissions of EtO directly into the atmosphere.
- 118. According to a former Sterigenics employee, who had responsibility for loading sterilized equipment for shipping from the Santa Teresa Plant to customers, Defendants demonstrated a lack of concern for EtO emissions from the Plant in a variety of ways.
- 119. For example, the facility is equipped with a color-coded air quality monitoring system that indicates to employees whether the concentration of EtO in ambient air is hazardous—red, yellow, and green, indicating respectively that EtO levels are unsafe, potentially unsafe, or safe. Beginning at least as of 2008, and likely earlier, Defendants caused facility shipping bays and large doors at the Plant to be left ajar for hours, or entire days, when EtO levels were unsafe or potentially unsafe so that the gas would dissipate and escape the facility into the surrounding air, returning the monitors to "green" status.
- 120. Employees at the Plant were also expected to continue working even if the air quality monitoring system indicated that the levels of EtO within the facility were of concern.
- 121. Another former Sterigenics employee, who had responsibility for custodial services at the Plant, also indicated that as of at least 2009, and likely earlier, Defendants caused facility shipping bays and large doors to be left ajar for long periods of time when EtO levels were too high, in order to allow the pollutant to escape.

- 122. That former employee further indicated that as part of his normal job duties, and beginning at least as of 2009, he had to hose down sterilization equipment on an at least monthly basis, and allow the "chamber scum" containing EtO and ethylene glycol residue to be freely washed down the drain.
- 123. A former Sterigenics employee also indicated that the Plant performed "favors" for other Sterigenics plants, including the San Diego facility. On an approximately weekly basis, during at least the period of 2009-2012, the San Diego facility shipped a load of sterilized equipment to the Santa Teresa Plant to aerate (and thus off-gas EtO) for a period of 24 hours.
- 124. As these shipments had been sterilized using EtO, but not aerated, they were off-gassing EtO during the shipping, receiving, and loading phases, including at the Santa Teresa Plant.
- 125. EtO emanating from the Santa Teresa Plant—whether from controlled or uncontrolled venting, stacks fitted with scrubbers and other control technologies, or uncontrolled sources such as facility doors and shipping bays, or unaerated equipment in transit—drifted from the Airport Road facility into the immediately surrounding business park and the residential communities in Santa Teresa only two miles away, and beyond.
- 126. As explained below, these significant emissions over a long period of time have caused a statistically significant increase in cancer risk for Santa Teresa residents.

D. DEFENDANTS' ETO RELEASES HAVE INJURED NEW MEXICO AND INCREASED THE RISK OF ADVERSE HEALTH EFFECTS IN SURROUNDING COMMUNITIES

127. In August 2018, EPA published results from its 2014 National Air Toxics Assessment study (NATA, as defined above).

- 128. The NATA study shows that Doña Ana County residents in the census tract likely suffering the most exposure to EtO have a cancer risk of **214.5543 per 1 million**, which is far in excess of the national average (approximately 30 per 1 million).
- 129. Crucially, the NATA study published in 2018 focuses on *reported EtO emissions* from 2014.
- 130. As alleged above, according to Defendants' self-reported emissions data, the Santa Teresa Plant released 5,761 pounds of EtO in 2014—down from over 10,000 pounds in 2013, over 12,000 pounds in 2012, and over 13,000 pounds in 2011. Further still, these reported figures do not account in any way for the uncontrolled emissions alleged above.
- 131. Accordingly, the 2014 data on which the cancer risk estimate is based drastically understates the actual risk in the Doña Ana County area when pre-2014 emissions levels, and unreported, uncontrolled emissions at any time, are taken into account.
- 132. Even setting these substantial limitations aside, the NATA study presents cause for concern.
 - 133. The NATA study furnishes the following material facts:
 - a. The only point source of EtO emissions in the Santa Teresa area is the Santa
 Teresa Plant;
 - b. In 2014, the Santa Teresa Plant released at least 2.8805 tons of EtO into air (equivalent to 5,761 lbs.)—the amount reported by Defendants;
 - c. On a *statewide* basis, New Mexico residents have a total cancer risk (based on air emissions exposure) of 24.2145 per 1 million, which is less than the national average;

- d. The 5,842 residents of census tract 35013001701, which includes Santa Teresa, have a total cancer risk (based on air emissions exposure) of 214.5543 per 1 million—nearly ten times the statewide risk level;
- e. That census tract has a higher total cancer risk (based on air emissions exposure) than any other census tract in New Mexico;
- f. Ethylene oxide emissions account for virtually all of the increased cancer risk in that census tract;
- g. Residents of nearby census tracts within Doña Ana County, including 35013000600 (2,801 residents), 35013001703 (3,029 residents), 35013001705 (3,192 residents), 35013001706 (3,749 residents), 35013001707 (5,749 residents), and 35013001805 (3,958 residents), and the County-level tract (35013000000), suffer elevated total cancer risk (based on air emissions exposure), due principally to EtO emissions in the region.
- 134. All told, the 2014 NATA study confirms that all of the residents of Doña Ana County, New Mexico (218,195 residents as of the filing of this Complaint) suffer an increased cancer risk as a result of toxic EtO emissions from the Santa Teresa Plant—and this estimate is based on substantially reduced 2014 EtO emissions, failing to account for far higher pre-2014 emissions and for unreported, uncontrolled emissions.
- 135. In addition to the 2014 NATA data based on self-reported emissions from the Santa Teresa Plant, the State conducted a presuit investigation that discovered alarming levels of EtO present in the ambient outdoor air in a four-mile area surrounding the facility.

- 136. This investigation included the collection and laboratory analysis of nineteen air samples. Every sample collected within the four-mile area around the Santa Teresa Plant revealed concentrations of EtO far in excess of the EPA IUR level.
- 137. As described above, these testing results demonstrate the presence of EtO in the Santa Teresa community's ambient air at up to 96 times the EPA's IUR cancer risk level.
- 138. Defendants' conduct has injured the State and the New Mexico public in several ways.
- 139. First, Defendants have significantly impaired the air quality in Doña Ana County since 1989, resulting in increased public health risks.
- 140. Next, the Santa Teresa Plant's EtO emissions have diminished property values in the affected communities, including the census tracts identified above.
- 141. Further, because the Santa Teresa Plant's EtO emissions have significantly increased the cancer risk of New Mexico residents residing in census tracts near the facility, including those tracts identified above, Defendants' practices result in increased healthcare costs incurred or to be incurred by the State in connection with State-sponsored healthcare plans and programs.
- 142. Because Defendants' conduct has significantly increased thousands of New Mexico residents' risk of serious adverse health effects, Defendants must fund a public health monitoring program designed to detect, assess, and treat medical disorders associated with EtO exposure, under State supervision.
- 143. Because Defendants' conduct has created an imminent and substantial endangerment to the public, Defendants must immediately cease any and all uncontrolled emissions or releases of EtO from the Santa Teresa Plant, pending trial in this matter.

E. DEFENDANTS' PERMITS DO NOT SHIELD THEM FROM LIABILITY

- 144. Defendants initiated construction of the Santa Teresa Plant in 1988 without a permit in violation of law.
- 145. Defendants received a permit in 1989 and sought, and obtained, various modifications to the original permit over time. These permits and permit modifications contained monitoring and reporting conditions, emission and environmental control parameters, and other terms that Defendants routinely violated.
- 146. During the initial permit application process and subsequent modification application processes, Defendants misrepresented or omitted material information from the New Mexico Environment Department and its predecessor agency.
 - 147. Among other misrepresentations and omissions, Defendants:
 - a. Failed to disclose—at any time—that they would circumvent the required environmental controls by, e.g., purposefully or negligently leaving shipping bays and other large facility doors open for hours, or longer, to dissipate elevated levels of EtO in the Plant;
 - b. Failed to disclose—at any time—that they would not accurately monitor and report total EtO emissions from the Plant;
 - c. Misrepresented or failed to disclose in the initial permit application process, in the first quarter of 1989, that significant quantities of EtO would be released from the Plant's aeration cell operations, which would not be connected to or controlled by the Plant's Deoxx scrubber;
 - d. Supplied incomplete and misleading air quality modeling in the first and second quarters of 1989, and modeling that included assumptions known to the company

to be inaccurate (e.g., that emissions would occur only during the same two fixed hours in any day);

- e. Made changes to the Plant's physical design after submitting permit applications in 1989, including changes to stack height;
- f. Misrepresented the viability or feasibility of continuous air emission monitoring technologies in 1989 and later;
- g. Underreported EtO emissions after obtaining a permit in 1989 in order to avoid implementing further environmental controls and to support the company's request to construct additional chambers.
- 148. Even if Defendants had lawfully obtained air quality permits, made no misrepresentations or omissions during the approval and modification processes, and complied with all permit conditions—which, as alleged above, they did not—such permits would not relieve Defendants from the obligation to otherwise comply with State law, including Defendants' common-law duties to the State, the local community in and around Santa Teresa, and the New Mexico public in general.
- 149. As a result of practices alleged above, Defendants have released potentially dangerous quantities of EtO through controlled and uncontrolled means into the Santa Teresa and Dona Ana County regions, have violated permit conditions requiring all EtO emissions to pass through scrubbers and other environmental control technologies, and breached other material terms on a continuous basis, including emission monitoring and reporting obligations, and otherwise violated New Mexico common and statutory law.

F. DEFENDANTS' UNFAIR OR DECEPTIVE REPRESENTATIONS

150. Defendants' revenue streams depend on obtaining contracts from equipment manufacturers, intermediaries, and equipment users for sterilization and fumigation services.

151. To obtain such contracts, Defendants seek to assure their clients and the public that their sterilization and fumigation practices are, among other things, environmentally sound and do not subject households proximate to their facilities to unreasonable risks of harm.

152. For example, in touting the "Sustainability" of its practices, the Sterigenics website, as of 2020, claims that "[w]e focus on continuous improvements and eliminating risk to protect people, the environment, and property."

153. Similarly, in their "Global Corporate Sustainability and Social Responsibility Report 2017," Defendants state, *inter alia*, that "[w]e are uncompromising in our commitment to health and well-being"; "[w]e are dedicated to protecting the environment and our communities"; and "[w]e focus on continuous improvement and eliminating risk to protect people, the environment and property."

154. Defendants have long promoted the environmental safety of their EtO sterilization and fumigation practices.

155. For example, the following statement, labeled "An Unwavering Commitment to Safety and the Environment," appeared on the Sterigenics website since at least August 2014 until at least February 2018:

While our reach is global, our commitment to customers, employees and the communities in which we operate remains local. Safety and Quality pervade our business goals, as does our commitment to environmentally responsible business practices.

Sterigenics has the following Safety and Environmental policies in place:

. . .

Environmental Policy:

Good citizenship is a key value for Sterigenics. We are dedicated to protecting the community and environment in which we work and complying with all applicable environmental regulations.

Sterigenics has a complete EH&S management system for the continuous improvement and compliance with all corporate and local environmental and safety requirements. This EH&S management system also meets ISO 14001 environmental and OSHAS 18001 safety standards. Sterigenics' facilities also utilize the latest engineering solutions for safety and environmental controls. Our key environmental and safety corporate metrics show continued improvements over the past 15 years of operations.

In pursuit of establishing new, environmentally responsible best practices, Sterigenics continues to focus on and improve their Sustainability Program. This program focuses resources and investments to meet the dynamic and evolving needs of our customers, while reducing our impacts on the environment. We strive to meet customers' needs and the vibrant growth of the global communities we serve.

At Sterigenics, we wouldn't have it any other way.

156. These and similar representations were made for the purpose of assuring Defendants' customers and the public that Defendants' operations are adequately protective of human health and the environment.

157. Such representations were unfair and/or deceptive because Defendants knowingly failed to adequately control their EtO emissions from the Santa Teresa Plant and caused injury to New Mexico and residents situated in proximity to the Plant, resulting in, among other things, a significantly increased risk of cancer for such residents.

158. Defendants' statements were also unfair and/or deceptive because they knowingly failed to disclose Defendants' failures to adequately control their EtO emissions from the Santa Teresa Plant, and indeed their purposeful subversion of environmental controls at the Plant, and that Defendants' conduct caused injury to New Mexico and residents situated in proximity to the Plant, resulting in, among other things, a significantly increased risk of cancer for such residents.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION PUBLIC NUISANCE

- 159. New Mexico realleges and incorporates the allegations set forth in paragraphs 1 through 158 as if fully stated herein.
- 160. New Mexico asserts this cause of action based on its inherent *parens patriae* authority.
- 161. Defendants emitted, discharged, or otherwise released toxic contaminants, including EtO, from the Santa Teresa Plant from 1989 to the present, and continue to do so, in a manner that created or participated in the creation of a public nuisance that is harmful to human and environmental health and obstructs the free use of New Mexico natural resources.
- 162. Defendants intentionally emitted, discharged, or otherwise released unsafe amounts of toxic contaminants, including EtO, from the Santa Teresa Plant since 1989, with the knowledge that they were causing and would continue to cause environmental contamination and threaten or impair public health.
- 163. Defendants' conduct and the presence of EtO annoys, injures, and endangers the comfort, repose, health, and safety of others.
- 164. Defendants' conduct and the presence of EtO interferes with and obstructs the public's free use and comfortable enjoyment of New Mexico natural resources.
- 165. Defendants' conduct and the presence of EtO in New Mexico natural resources are injurious to human and environmental health.
- 166. An ordinary person would be reasonably annoyed or disturbed by the presence of toxic EtO that endangers human health, and degrades air quality.
- 167. The seriousness of the risks created by this conduct far outweighs any social utility of Defendants' conduct.

- 168. The rights, interests, and inconvenience to New Mexico and the general public far outweighs the rights, interests, and inconvenience to Defendants, who profited significantly from the use of EtO for decades.
 - 169. Defendants' conduct caused harm to the State and its citizens.
- 170. New Mexico has been damaged by Defendants' conduct, including Defendants' unreported, uncontrolled EtO emissions.
- 171. The State is incurring and will continue to incur costs and losses as a result of Defendants' conduct.
- 172. Defendants' conduct and the public nuisance they have created has also caused property values in the affected census tracts to decline.
- 173. Defendants knew their conduct in emitting, discharging, or otherwise releasing toxic EtO would cause such injuries to the State and the New Mexico public.
 - 174. Accordingly, Defendants had a duty to cease such conduct but failed to do so.
 - 175. Defendants also had a duty to warn about the dangers of EtO, but failed to do so.
- 176. As a direct and proximate result of Defendants' creation of a public nuisance, New Mexico has suffered and will suffer monetary losses, including increased past and future healthcare costs, and other damages in amounts to be proven at trial.
- 177. To abate the public nuisance, the State seeks an order requiring Defendants to fund a public health monitoring program designed to detect, assess, and treat medical disorders associated with EtO exposure, under State supervision.
- 178. Because Defendants' conduct as alleged herein was malicious, willful, reckless, and/or wanton, the State is entitled to seek, and does seek, punitive damages sufficient to punish Defendants and to deter Defendants and others from engaging in similar conduct in the future.

SECOND CAUSE OF ACTION VIOLATIONS OF THE NEW MEXICO PUBLIC NUISANCE STATUTE, NMSA 1978 §§ 30-8-1, ET SEQ.

- 179. New Mexico realleges and incorporates the allegations set forth in paragraphs 1 through 178 as if fully stated herein.
- 180. New Mexico asserts this cause of action based on its inherent *parens patriae* authority.
- 181. New Mexico asserts this cause of action pursuant to NMSA 1978 §§ 30-8-1, et seq. (the Public Nuisance Statute, as defined above).
- 182. The Public Nuisance Statute renders unlawful "knowingly creating, performing or maintaining anything affecting any number of citizens without lawful authority which is either (A) injurious to public health, safety, morals or welfare; or (B) interferes with the exercise and enjoyment of public rights[.]" NMSA 1978 § 30-8-1(A)-(B).
- 183. The Attorney General is authorized to enforce the Public Nuisance Statute in court by seeking abatement from "any person, corporation or association of persons who shall create, perform or maintain a public nuisance." NMSA 1978 § 30-8-8.
- 184. Defendants have knowingly created, performed, or maintained a public nuisance injurious to public health, safety, and welfare, which interferes with the New Mexico public's right to avoid dangerous, carcinogenic substances in natural resources.
- 185. Defendants emitted, discharged, or otherwise released toxic contaminants, including EtO, from the Santa Teresa Plant from 1989 to the present, and continue to do so, in a manner that created or participated in the creation of a public nuisance that is harmful to human and environmental health and obstructs the free use of New Mexico natural resources.
- 186. Defendants intentionally emitted, discharged, or otherwise released toxic contaminants, including EtO, from the Santa Teresa Plant since 1989, with the knowledge that

they were causing and would continue to cause environmental contamination and threaten and impair public health.

- 187. Defendants' conduct and the presence of EtO annoys, injures, and endangers the comfort, repose, health, and safety of others.
- 188. Defendants' conduct and the presence of EtO interferes with and obstructs the public's free use and comfortable enjoyment of New Mexico natural resources.
- 189. Defendants' conduct and the presence of EtO in New Mexico natural resources are injurious to human and environmental health.
- 190. An ordinary person would be reasonably annoyed or disturbed by the presence of toxic EtO that endangers human health, and degrades air quality.
- 191. The seriousness of the risks created by this conduct far outweighs any social utility of Defendants' conduct.
- 192. The rights, interests, and inconvenience to New Mexico and the general public far outweighs the rights, interests, and inconvenience to Defendants, who profited significantly from the use of EtO for decades.
 - 193. Defendants' conduct caused harm to the State and its citizens.
 - 194. New Mexico has been damaged by Defendants' EtO emissions.
- 195. The State is incurring and will continue to incur costs and losses as a result of Defendants' conduct.
- 196. Defendants' conduct and the public nuisance they have created has also caused property values in the affected census tracts to decline.
- 197. Defendants knew their conduct in emitting, discharging, or otherwise releasing toxic EtO would cause such injuries to the State and the New Mexico public.

- 198. Accordingly, Defendants had a duty to cease such conduct but failed to do so.
- 199. Defendants also had a duty to warn about the dangers of EtO, but failed to do so.
- 200. As a direct and proximate result of Defendants' creation of a public nuisance, New Mexico has suffered and will suffer monetary losses, including increased past and future healthcare costs, and other damages in amounts to be proven at trial.
- 201. To abate the public nuisance, the State seeks an order requiring Defendants to fund a public health monitoring program designed to detect, assess, and treat medical disorders associated with EtO exposure, under State supervision.
- 202. Because Defendants' conduct as alleged herein was malicious, willful, reckless, and/or wanton, the State is entitled to seek, and does seek, punitive damages sufficient to punish Defendants and to deter Defendants and others from engaging in similar conduct in the future.

THIRD CAUSE OF ACTION STRICT LIABILITY

- 203. New Mexico realleges and incorporates the allegations set forth in paragraphs 1 through 202 as if fully stated herein.
- 204. New Mexico asserts this cause of action based on its inherent *parens patriae* authority.
- 205. Defendants' operation of the Santa Teresa Plant, including the handling, emission, discharge, and release of toxic EtO since 1989, is an ultahazardous and/or abnormally dangerous activity under New Mexico law.
- 206. Accordingly, Defendants are held to a heightened duty of care toward the public and those who may be injured due to Defendants' conduct, and are strictly liable for all injuries resulting from their handling, emission, discharge, or release of EtO from the Santa Teresa Plant.
 - 207. Defendants' conduct caused harm to the State and its citizens.

- 208. New Mexico suffered and continues to suffer damage from Defendants' handling, emission, discharge, and release of EtO.
- 209. The State is incurring and will continue to incur costs and losses as a result of Defendants' conduct.
- 210. Defendants' conduct and the ultrahazardous and/or abnormally dangerous activities in which they engaged have also caused property values in affected census tracts to decline.
- 211. As a direct and proximate result of Defendants' ultrahazardous and/or abnormally dangerous activities, New Mexico has suffered and continues to suffer monetary losses, including increased past and future healthcare costs, and other damages in amounts to be proven at trial.
- 212. Because Defendants' conduct as alleged herein was malicious, willful, reckless, and/or wanton, the State is entitled to seek, and does seek, punitive damages sufficient to punish Defendants and to deter Defendants and others from engaging in similar conduct in the future.

FOURTH CAUSE OF ACTION NEGLIGENCE

- 213. New Mexico realleges and incorporates the allegations set forth in paragraphs 1 through 212 as if fully stated herein.
- 214. New Mexico asserts this cause of action based on its inherent *parens patriae* authority.
- 215. Defendants failed to exercise ordinary care because a reasonably careful company that knew or learned of the toxicity, carcinogenicity, harmfulness to humans, and harmfulness to the natural environment of chemicals being emitted, discharged, or otherwise released from its facility, in the manner and quantity that such emission, discharge, or release occurred at the Santa Teresa Plant, would not continue to emit, discharge, or release such chemicals in the same manner

or quantity, would warn of the hazards introduced as a result, and at a minimum would take steps to enhance the safety of its operations as soon as possible.

- 216. Defendants failed to exercise ordinary care because a reasonably careful company would not continue to use EtO in mass quantities and to the extent that Defendants used and emitted, discharged, or otherwise released EtO, and would at an absolute minimum ensure that all appropriate environmental safeguards and controls were effective and in working order.
- 217. Defendants were grossly negligent because they failed to exercise even slight care, placing revenue and profit generation above human and environmental health and safety.
- 218. Defendants owed the State and its citizens a duty of care in the operation of the Santa Teresa Plant, and the use and disposal of toxic chemicals including EtO.
- 219. It was foreseeable to Defendants that their controlled and uncontrolled EtO emissions would end up in New Mexico's environment and result in harmful exposure of New Mexico residents in nearby workplaces and residential communities.
- 220. Defendants' negligent conduct and the presence of EtO in New Mexico natural resources caused injury to the physical and economic health and well-being of New Mexico citizens.
- 221. As a direct and proximate result of Defendants' negligent conduct, New Mexico has suffered and continues to suffer monetary losses, including increased past and future healthcare costs, and other damages in amounts to be proven at trial.
- 222. Because Defendants' conduct as alleged herein was malicious, willful, reckless, and/or wanton, the State is entitled to seek, and does seek, punitive damages sufficient to punish Defendants and to deter Defendants and others from engaging in similar conduct in the future.

FIFTH CAUSE OF ACTION TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

- 223. New Mexico realleges and incorporates the allegations set forth in paragraphs 1 through 222 as if fully stated herein.
- 224. Absent a temporary restraining order and preliminary injunction, the State will suffer immediate and irreparable injury, loss or damage.
- 225. Defendants, by their actions, have caused and continue to cause an unreasonable and substantial prejudice to the public health and welfare.
- 226. Defendants' uncontrolled emissions of EtO, a known carcinogen, into the atmosphere near residences and places of business in Santa Teresa injure or threaten to injure the health of people living and working near the Santa Teresa Plant, have caused fear in the community due to the threat to public health, and interfere with the enjoyment and use of their homes, work places, public places, and environment.
- 227. As a consequence of the conduct alleged herein, Defendants have created and maintained a public nuisance and breached their duties to the State and the public.
- 228. Due to the urgency of the facts presented in this Complaint, and the imminent and substantial endangerment suffered by the New Mexico public as a result of Defendants' conduct, the State is without an adequate remedy at law.
- 229. Absent a temporary restraining order and preliminary injunction requiring Defendants to immediately cease any and all uncontrolled emissions or releases of EtO from the Santa Teresa Plant, the State will be irreparably injured, and violations of the common and statutory law as outlined herein will continue unless and until this Court grants such temporary and preliminary relief and, after trial, permanent injunctive relief.
- 230. The threatened injury outweighs any damage the injunction might cause Defendants.

231. There is a substantial likelihood the State will prevail on the merits of this case.

SIXTH CAUSE OF ACTION VIOLATIONS OF NEW MEXICO UNFAIR PRACTICES ACT, 1978 NMSA §§ 57-12-1, ET SEQ.

- 232. New Mexico realleges and incorporates the allegations set forth in paragraphs 1 through 231 as if fully stated herein.
- 233. This is a claim for restitution and disgorgement, injunctive relief, and civil penalties under the Unfair Practices Act. NMSA 1978 §§ 57-12-1, et seq.
- 234. Under the Unfair Practices Act, "[u]nfair or deceptive trade practices and unconscionable trade practices in the conduct of any trade or commerce are unlawful." NMSA 1978 § 57-12-3.
- 235. An "unfair or deceptive trade practice" is an act "specifically declared unlawful pursuant to the Unfair Practices Act, a false or misleading oral or written statement, visual description or other representation of any kind knowingly made in connection with the sale, lease, rental or loan of goods or services ... by a person in the regular course of his trade or commerce, which may, tends to or does deceive or mislead any person[.]" NMSA 1978 § 57-12-2(D). Omissions of material information are actionable under the Unfair Practices Act.
- 236. Unfair or deceptive trade practices include, *inter alia*, representing that services have "characteristics, … uses, [or] benefits … that they do not have"; that services "are of a particular standard, quality or grade … if they are of another"; and "using exaggeration, innuendo or ambiguity as to a material fact or failing to state a material fact if doing so deceives or tends to deceive." NMSA 1978 §§ 57-12-2(D)(5), (7), (14).
- 237. By representing the environmental soundness of their EtO utilization and industrial sterilization and fumigation practices using EtO, Defendants made unfair and/or deceptive representations in violation of the Unfair Practices Act.

- 238. Similarly, by representing the level and degree of risk to human health associated with their EtO utilization and industrial sterilization and fumigation practices using EtO, Defendants made unfair and/or deceptive representations in violation of the Unfair Practices Act.
- 239. As alleged above, Defendants' various environmental and human health representations—as made to the State and State employees, and as made to Defendants' customers and clients and the public—were unfair and/or deceptive because Defendants knowingly failed to adequately control their EtO emissions from the Santa Teresa Plant and caused injury to New Mexico and residents situated in proximity to the Plant, resulting in, among other things, a significantly increased risk of cancer for such residents.
- 240. Defendants' statements were also knowingly unfair and/or deceptive because they failed to disclose Defendants' failures to adequately control their EtO emissions from the Santa Teresa Plant and that Defendants' conduct caused injury to New Mexico and residents situated in proximity to the Plant, resulting in, among other things, a significantly increased risk of cancer for such residents.
- 241. Accordingly, Defendants knowingly misrepresented that their EtO sterilization and fumigation services had characteristics, uses, or benefits that they did not, in fact, possess (namely, environmental and human health protection); misrepresented that those services were of a particular standard, quality or grade (namely, protective of environmental and human health) when, in fact, they were not; and failed to state that those services would expose New Mexico communities to dangerous levels of EtO or to adverse health effects associated with EtO exposure, including cancer, in violation of the Unfair Practices Act.
- 242. Each unfair or deceptive trade practice alleged herein was carried out knowingly and willfully because Defendants were actually aware that their EtO sterilization and fumigation

services posed unreasonable dangers to the environment and residents in proximity to the Santa Teresa Plant, and/or in the exercise of reasonable diligence, Defendants should have been aware that their statements were unfair and/or deceptive for those reasons.

- 243. Defendants' unfair or deceptive representations and omissions as alleged herein are of the type that tended to deceive and/or mislead Defendants' customers or clients, as well as New Mexico and residents of New Mexico, that Defendants' EtO sterilization and fumigation services were safe for the environment and human health.
- 244. The State of New Mexico seeks restitution and disgorgement under NMSA 1978 § 57-12-8(B); injunctive relief adequate to remedy Defendants' violations of the Unfair Practices Act, including an order requiring Defendants to fund a public health monitoring program designed to detect, assess, and treat medical disorders associated with EtO exposure, under NMSA 1978 § 57-12-8(B); and all recoverable penalties under NMSA 1978 § 57-12-11.

JURY DEMAND

New Mexico respectfully requests trial by jury on all claims so triable.

PRAYER FOR RELIEF

New Mexico prays for judgment against Defendants, jointly and severally, as follows:

- Damages according to proof;
- B. Declaratory relief, including an order declaring that the conduct alleged herein has violated New Mexico law;
- C. Temporary and preliminary injunctive relief pending trial, including a temporary restraining order and preliminary injunction requiring Defendants to immediately cease any and all uncontrolled emissions or releases of EtO from the Santa Teresa Plant, and a permanent injunction upon conclusion of trial, including an Order prohibiting Defendants from causing,

making, facilitating, or otherwise allowing any uncontrolled emission or release of EtO from the Santa Teresa Plant, including, but not limited to:

- 1. Leaving facility doors, shipping bays, or other means of egress open when not in use;
- 2. Leaving sterilization chamber doors, aeration room doors, and other interior doors open when not in use;
- 3. Allowing off-gassing associated with the storing, transporting, or handling of EtO prior to charging of sterilization chambers;
- 4. Allowing the off-gassing of EtO from under-controlled aeration rooms, from transfer of sterilized product from sterilizer chambers to aeration rooms, and from sterilized product removed from aeration rooms; and
- 5. Allowing any EtO to escape through pipes, equipment, vents, stacks, or other point sources prior to filtration or processing through fully functioning emission controls.
- D. Further injunctive relief, including the award of past, present, and future costs to fully abate the public nuisance and an order requiring Defendants to fund a public health monitoring program designed to detect, assess, and treat medical disorders associated with EtO exposure;
- E. An order requiring Defendants to disgorge all revenues obtained as a result of violations of the Unfair Practices Act, and to make restitution to all persons of money, property, or other things received from them in any transaction related to Defendants' violations of the Unfair Practices Act;
 - F. Civil penalties of \$5,000 per willful violation of the Unfair Practices Act;

- G. Award of punitive damages sufficient to punish Defendants for malicious, willful, reckless, and/or wanton misconduct and to deter Defendants and others from engaging in similar misconduct in the future;
 - H. Litigation costs and attorneys' fees as permitted by law;
- I. Pre-judgment and post-judgment interest on all monies awarded, as permitted by law;
 - J. Such other and further relief as the Court deems just and proper.

DATED: December 22, 2020

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